

Indefiniteness Rejection

Claim 8 was rejected under 35 USC §112, second paragraph. (Paper No. 15 at 3). In making the rejection, the Examiner contended only that:

The term “comprising” cited in claim 8 is inclusive and fails to exclude **unrecited steps**. The use of the term comprising to introduce claimed structure means that the ingredients covered by these claims may involve more elements than those positively recited. *Ex parte Gottzein et al.*, 168 USPQ 176 (PTO Bd. App. 1969). Comprising leaves the claim open for inclusion of unspecified ingredients even in major amounts. (*Id.* at 3-4.)

For the reasons set forth below, the rejection is traversed.

As is well settled, all that is required to comply with 35 USC §112, second paragraph, is that the metes and bounds of what is claimed be determinable with a reasonable degree of precision and particularity. *Ex parte Wu*, 10 USPQ2d 2031, 2033 (BPAI 1989).

Claim 8 recites “A composition comprising....” There is nothing vague or indefinite about any of the recited compositions. One skilled in the art would readily recognize what is being claimed. Nothing more is required, and the Examiner has not articulated any facts to support the rejection. For this reason alone, the rejection should be withdrawn.

Moreover, the use of the transitional term “comprising” is so common place in patent claims to be endorsed by the MPEP. “The transitional phrases ‘comprising’, ‘consisting essentially of’ and ‘consisting of’ define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.” MPEP § 2111.03 (8th Ed. August 2001, p. 2100-49). In

short, “comprising” is a term of art that is clearly recognized by the PTO. Thus, the use of “comprising” in a claim by itself is insufficient to support a rejection under § 112, second paragraph.

Moreover, the rejection appears to focus on the breadth imparted to claim 8 based on the recitation of “comprising.” Breadth alone, however, does not render a claim indefinite. As the MPEP also makes clear, “BREADTH IS NOT INDEFINITENESS” (See Title of MPEP § 2173.04 (8th Ed. August 2001, p. 2100-195).

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. (*Id.*)

For this additional reason, the rejection is insufficient as a matter of fact and law, and must be withdrawn.

Anticipation Rejections

Claims 1-3 and 24-25 were rejected under 35 USC §102(b) as anticipated by Benesova, V., Phytochemistry of Common Marcantial Mosses, Marchantiopsida (Hepaticopsids), Rastit. Resur. 21(4), p. 523-9 (1985). (“Benesova”).¹ (Paper No. 15 at 2.)

For the reasons set forth below, the rejection, respectfully is traversed.

Benesova discloses “the most characteristic chem[ical] features of the Calobryales and Jungermanniales mosses.”

¹ The Examiner has only made of record and appears to rely only on an abstract of the article in question. Accordingly, the rejection will be addressed as relying on the abstract alone.

In making the rejection, the Examiner contended only that Benesova discloses "an erost-5-en-3-ol, docosanoate." (Paper No. 15 at 2.)

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir 1984).

We note that claim 1 recites a "phytosterol ester compound produced from a reaction of a phytosterol with eicosapentaenoic acid or docosahexaenoic acid" Accordingly, the claimed compounds are esters of ***polyunsaturated*** fatty acids. Benesova discloses a docosanoate which is a ***saturated*** fatty acid ester. Thus, the rejection fails to identify where in Benesova a ***polyunsaturated*** fatty acid of the type claimed is disclosed. For at least this reason, the rejection is factually insufficient and should be withdrawn.

Claims 1-3 and 24-25 were rejected under 35 USC §102(b) as anticipated by Lusby *et al.*, Analysis of sterol esters by capillary gas chromatography-electron impact and chemical ionization-mass spectrometry, *Lipids* 19(11), p. 888-901 (1984) ("Lusby").² (Paper No. 15 at 3.)

For the reasons set forth below, the rejection, respectfully is traversed.

Lusby discloses the separation and structural analysis of "[s]ynthetic mixt[ures] of C40 to C47 sterol esters."

In making the rejection, the Examiner contended only that Lusby discloses "ergost. -5-3-ol, 9, 12, 15-octadecatrienoate (having three double bonds)." (Paper No. 15 at 3.)

As noted above, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d at 1498.

We note that claim 1 recites a "phytosterol ester compound produced from a reaction of a phytosterol with eicosapentaenoic acid or docosahexaenoic acid...." Accordingly, the claimed compounds are phytosterol esters produced from eicosapentaenoic acid or docosahexaenoic acid. The rejection, however, fails to identify where in Lusby there is a disclosure of a "phytosterol ester," let alone a phytosterol ester produced from eicosapentaenoic acid or docosahexaenoic acid having the property of being a liquid at from -20°C to 20°C as claimed.

Because, Lusby does not disclose each and every element of the claimed compound, the rejection fails to make out a *prima facie* case and should be withdrawn.

Claims 1-3 and 24-25 also were rejected under 35 USC §102(b) as anticipated by Austin, P. *et al.*, Chemical study of Prunus puddum (stem bark) and Prunus cornuts (stem bark and wood), Indian J. Chem., 7(1), p. 43-48 (1969) ("Austin").³ (Paper No. 15 at 3.)

For the reasons set forth below, the rejection, respectfully is traversed.

Austin discloses the results of a chemical analysis of "[t]he stem bark of P. puddum and the stem bark and wood of P. cornuta."

³ The Examiner has only made of record and appears to rely only on an abstract of the article in question. Accordingly, the rejection will be addressed as relying on the abstract alone.

In making the rejection, the Examiner contended only that Austin discloses "stigmast-5-en-ol, docosanoate." (Paper No. 15 at 2.)

As noted above, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d at 1498.

We again note that claim 1 recites a "phytosterol ester compound produced from a reaction of a phytosterol with eicosapentaenoic acid or docosahexaenoic acid...." Accordingly, the claimed compounds are esters of ***polyunsaturated*** fatty acids. Austin discloses a docosanoate, which is a ***saturated*** fatty acid ester. Thus the rejection fails to identify where in Austin a polyunsaturated fatty acid if the type claimed is disclosed. For at least this reason, the rejection is factually insufficient and should be withdrawn.

The Examiner also asserted that the "[a]mended claims contain a limitation of being the compounds liquid at temperatures from about -20C to about 20C," and that "the property of being an oil or liquid at give temperature is inherent with the compound and is not critical for the invention." (Paper No. 15 at 3.) The relevance of this assertion is not understood. Respectfully, it is submitted that a claim element may not be summarily dismissed or ignored based on a bald allegation that such a claim element is not "critical for the invention." Here the rejection provides no evidence to support the "critical for the invention" conclusion.

The rejection also does not provide any facts to support the assertion that a liquid state at temperatures from 20°C to -20°C is an inherent feature of the

³ The Examiner has only made of record and appears to rely only on an abstract of the article in question. Accordingly, the rejection will be addressed as relying on the abstract alone.

compounds identified by the Examiner. In short, the rejection offers no factual basis for completely ignoring a claim limitation.

Thus, the rejection fails to make out a *prima facie* case for anticipation and for this reason also, the rejection should be withdrawn.

In short, the § 102(b) rejections fail to show that the cited documents disclose either the chemical structures claimed, or the physical property claimed. **None** of the claim limitations are accounted for by the rejections. Accordingly, the rejections all fall far short of the showing required to support a rejection under 35 USC § 102(b), and should be withdrawn.

Obviousness Rejection

Claim 8 was rejected under 35 USC § 103 as unpatentable over Mitchell, U.S. Patent No. 4,588,717 ("Mitchell"), Kamarei *et al.*, U.S. Patent No. 4,879,312 ("Kamarei"), and Miettinen *et al.*, WO 92/19640 ("Miettinen"). (Paper No. 15 at 5).

For the reasons set forth below the rejection, respectfully is traversed.

Mitchell discloses "vitamin steroid supplements ... [comprising] one or more phytosterol esters...." (Col. 5, lines 23-24.) To form the phytosterol esters, Mitchell discloses condensing phytosterols with fatty acids having from about 18 to about 20 carbon atoms in the main chain and at least two carbon-to-carbon double bonds. (Col. 5, lines 55-60.)

Kamarei discloses a "method for provoking or enhancing angiogenesis in an individual subject by administering to the subject an angiogenically effective amount of an angiogenically active ω -3 polyunsaturated fatty acid." (Col. 3, lines 13-17.)

Kamarei specifically discloses the administration of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). (Col. 3, lines 18-19.)

Miettinen discloses a β -sitostanol fatty acid ester or fatty acid ester mixture that lowers serum cholesterol levels and processes for producing the ester or ester mixture. (Abstract.) Miettinen discloses esterifying a β -sitostanol mixture containing approximately 6% campestanol with different fatty acid ester mixtures using "commonly known" interesterification techniques. (Page 6, lines 26-32.)

In making the rejection, the Examiner asserted that Mitchell discloses "vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigmasterol and taxasterol, in various combinations." (Paper No. 15 at 5.) The rejection further asserted that Mitchell discloses "[f]atty acid have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups (lines 2-15, Col. 6) and at least two double bonds such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters..." and that "the reaction between any given phytosterol and any given fatty acid is essentially the same...." (*Id.* at 5-6.)

The Examiner asserted that Kamarei discloses "that a diet rich in omega-3-fatty acids has beneficial effects in humans...." (Paper 15 at 6.) The rejection also asserted that Kamarei discloses that "one of n-3 PUFA i.e. EPA and DHA reduces triglyceride and very low-density lipoprotein (VLDL) serum levels and reduces whole blood viscosity." (*Id.*)

The Examiner asserted that Miettinen discloses "a composition of β -sitostanol fatty acid ester mixture or fatty acid ester mixture" and that the "physical properties can be modified easily by altering the fatty acid composition of the mixture."

(*Id.*) The Examiner further asserted that Miettinen discloses a “fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol.” (*Id.*)

The Examiner conceded however, that the “claims differ from the reference in claiming a composition containing combination of phytosterol ester compound produced by the reaction of phytosterol and specific fatty acids eicosahexaenoic acid (20-carbons) and/or docosahexaenoic acid (22-carbons), whereas prior art teaches compounds with fatty acids especially containing approximately 2-22 carbon atoms.” (*Id.* at 7.) The Examiner further asserts that the claimed invention is “a selection of prior art teachings.” (*Id.*)

The Examiner then concluded that “it would have been obvious ... to employ **phytosterols composition in combination with omega-fatty acids** and methods for lowering cholesterol and triglycerides in blood serum ... because these agents are known individually for the treatment of the same disorders.” (*Id.*) The rejection asserts that the “[m]otivation is to prepare additional beneficial **composition of sterols with unsaturated fatty acids** such as omega-3-fatty acids, EPA, DHA ... because this use has been taught by the prior art for the said compositions.” (*Id.* at 8.)

Initially, we note that the Examiner appears to reject claim 8 on the basis that it is a “selection of prior art teachings.” (Paper No. 15 at 7.) That is simply the wrong standard. Whether or not a claimed invention is a selection of prior art teachings is irrelevant to a determination of obviousness. The Federal Circuit has addressed this issue numerous times and has observed that most patentable inventions are a combination of old elements. *Environmental Designs, Ltd. v. Union Oil Company of California*, 218 USPQ2d 865, 870 (Fed. Cir. 1983) (“That all elements of an invention

may have been old (the normal situation), or some old and some new, or all new, is however, simply irrelevant. Virtually all inventions are combinations and virtually all are combinations of old elements."). Thus, to the extent the Examiner relies on the "selection of prior art teaching" standard, the rejection is deficient as a matter of law and must be withdrawn for this reason alone.

We also note that "phytosterols composition in combination with omega-fatty acids..." is asserted to be rejected by the Examiner. (See Paper No. 15 at 7.) That, however, is not what is claimed. Pending claim 8 is reproduced below:

8. A composition comprising an admixture of the compounds (a) and (b) wherein **(a) is a phytosterol ester compound** produced from a reaction of a phytosterol with eicosapentaenoic acid or docosahexaenoic acid; and **(b) is a second ester** which is the product of an esterification reaction between a phytosterol and/or a phytostanol and (i) a fatty acid having less than 18 or more than 22 carbon atoms and at least three carbon-carbon double bonds and/or; (ii) a fatty acid having from 18 to 22 carbon atoms and less than three carbon-carbon double bonds.

In short, claim 8 claims a composition containing an admixture of a phytosterol ester and a specifically defined second ester. However, the rejection is apparently directed to a composition containing "sterols [and] unsaturated fatty acids" or to "phytosterols composition in combination with omega-fatty acids." (Paper No. 15 at 7-8.)

Accordingly, the rejection is not directed to the invention claimed by the applicants. For this reason also the rejection is moot on its face and must be withdrawn.

The rejection is silent as to the "second ester" recited in clause (b) of claim 8. The rejection fails to identify a disclosure of the specific esters embraced

thereby nor does it identify a suggestion or motivation to claim the second ester in the way recited by claim 8. For this reason as well the rejection should be withdrawn.

Claims 1-6, 24 and 25 were rejected under 35 USC §103 as unpatentable over Miettinen and Mitchell. (Paper No. 15 at 8).

For the reasons set forth below the rejection, respectfully is traversed.

Miettinen and Mitchell are summarized above.

In making the rejection, the Examiner asserted that Miettinen discloses "a composition of b-sitosterol fatty acid ester mixture or fatty acid ester mixture" and that "physical properties can be modified easily by altering the fatty acid composition of the mixture." (Paper 15 at 9.) The rejection further asserted that Miettinen discloses "the fatty acid composition of the b-sitosterol can also be selected so as to contain large amounts of monoenes and polyenes, whereby efficacy on lowering the cholesterol levels in serum are enhanced." (*Id.*)

The Examiner asserted that Mitchell discloses "vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigmasterol and taxasterol, in various combinations." (Paper No. 15 at 8.) The rejection further asserted that Mitchell discloses "[f]atty acid have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups ... and at least two double bonds such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters..." and that "the reaction between any given phytosterol and any given fatty acid is essentially the same...." (*Id.* at 8-9.)

The Examiner conceded however, that the "claims differ from the reference in claiming reaction of phytosterol with specific fatty acids i.e.

docosahexaenoic acid and eicosahhexaenoic⁴ whereas prior art teaches reaction product of phytosterol with fatty acids especially containing approximately 2-22 carbon atoms.” (*Id.*)

To fill the acknowledged gap, the Examiner asserted that the “[i]nstant claims are a **selection of prior art** teachings.” (*Id.*)

The Examiner then concluded that “[i]t would have been **obvious** ... to **prepare** additional beneficial composition by selecting any fatty acids for example, docosahexaenoic acid and eicosahexaenoic⁵ acid from fatty acid 2-22 taught by the prior art.” (*Id.* at 9-10.) Further, the Examiner asserted that “[t]here has been **ample motivation provided by the prior art** to prepare the instant invention.” (*Id.* at 9-10.)

As is fundamental, “[t]o establish a *prima facie* case of obviousness ... the prior art reference must teach or suggest all the claimed limitations.” *In re Royka*, 180 USPQ 580 (C.C.P.A. 1974); and MPEP 706.02(j), 2143, and 2143.03. Additionally, a *prima facie* case of obviousness must be based on facts. *In re Freed*, 165 USPQ 570, 571-72 (C.C.P.A. 1970). When the rejection is not supported by facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (B.P.A.I. 1993).

Initially, we note that the rejection completely ignores an element of, e.g., claim 1. Specifically, the rejection identifies nothing in Miettinen or Mitchell, alone or in combination, that discloses or suggests that the compound is a liquid between about -20°C and 20°C. Thus, the rejection contains a factual gap. For this reason alone the rejection should be withdrawn.

⁴ We note that the Examiner uses the term “eicosahhexaenoic acid” when referring to one of the fatty acids recited in claim 1. Claim 1, however, recites “eicosapentaenoic acid.” In this Response, we assume that the Examiner intended eicosapentaenoic acid when eicosahhexaenoic acid was written. If this assumption is incorrect, the Examiner is requested to clarify this issue on the record.

We also note that the rejection relies on “**selection of prior art**” and “**obvious ... to prepare**” standards to reject the claims under § 103. (Paper 15 at 9.) The statute, as well as, years of case law commands that the Examiner make the obviousness determination based on whether the “subject matter as a whole would have been obvious at the time the application was filed.” (See 35 USC § 103). Thus, whether or not the claimed invention is a “selection of prior art” or would have been “obvious to prepare” is irrelevant to the required analysis. *Environmental Designs, Ltd. v. Union Oil Company of California*, 218 USPQ at 870 and *In re Wright*, 6 USPQ2d 1959, 1960-61 (Fed. Cir. 1988) *overruled on other grounds*. Because the rejection relies on the wrong standard, it should be withdrawn for this reason as well.

A *prima facie* case of obviousness requires that the rejection describe with specificity **why** one skilled in the art would have combined two references to arrive at the claimed invention. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (CAFC 1999). When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). The factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine “**must be based on objective evidence of record**.” *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

⁵ See footnote 4.

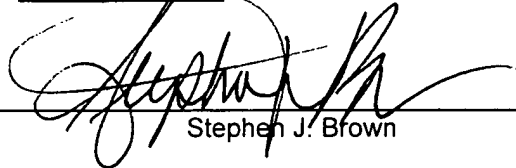
Here, the rejection merely asserts that "[t]here has been **ample motivation provided by the prior art** to prepare the instant invention." (*Id.* at 9-10.)

The rejection points to nothing in Miettinen or Mitchell which discloses or suggests the combination proposed by the Examiner to arrive at the claimed invention. The rejection merely concludes that one would have been motivated to combine the cited documents as suggested, but does not describe with any specificity **why** one would be motivated to combine the documents. Yet this too was the Examiner's burden. Accordingly, the rejection fails to set forth a *prima facie* case for obviousness. For this reason also, the rejection should be withdrawn.

In sum, the rejection is insufficient as a matter of fact and law. Accordingly, withdrawal of the rejection of claims 1-6, 24, and 25 is requested.

In view of the foregoing, favorable action on the merits including entry of the amendment, withdrawal of each of the rejections, and allowance of all the claims, respectfully, is solicited.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on January 27, 2003.



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Respectfully submitted,

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